

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:075. Certificate of Need nonsubstantive review.

5 RELATES TO: KRS 216B.010, 216B.095, 216B.455, 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the

8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need

9 Program and to promulgate administrative regulations as necessary for the program.

10 This administrative regulation establishes the requirements necessary for consideration
11 for nonsubstantive review of applications for the orderly administration of the Certificate
12 of Need Program.

13 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

14 (2) "Certificate of Need Newsletter" means the monthly newsletter that is published
15 by the cabinet regarding certificate of need matters and is available on the Certificate of
16 Need w[W]eb site at <http://chfs.ky.gov/ohp/con>.

17 (3) "Days" means calendar days, unless otherwise specified.

18 (4) "Formal review" means the review of applications for certificate of need which
19 are reviewed within ninety (90) days from the commencement of the review as provided
20 by KRS 216B.062(1) and which are reviewed for compliance with the review criteria set
21 forth at KRS 216B.040 and 900 KAR 6:070.

1 (5) "Nonsubstantive review" is defined by KRS 216B.015(17).

2 (6) "Public information channels" means the Office of Communication and
3 Administrative Review in the Cabinet for Health and Family Services.

4 (7) "Public notice" means notice given through:

5 (a) Public information channels; or

6 (b) The cabinet's Certificate of Need Newsletter.

7 (8) "Therapeutic cardiac catheterization outcomes" means in hospital mortality rates,
8 door to balloon time, door to balloon time less than or equal to ninety (90) minutes,
9 Percutaneous Coronary Intervention (PCI) related cardiac arrests and emergency open
10 heart surgeries performed as a result of the PCI.

11 Section 2. Nonsubstantive Review. (1) The cabinet shall grant nonsubstantive
12 review status to applications to change the location of a proposed health facility or to
13 relocate a licensed health facility only if:

14 1. There is no substantial change in health services or bed capacity; and

15 2. The change of location or relocation is within the same county[- or

16 ~~— (b) The change of location for a psychiatric residential treatment facility is within the~~
17 ~~same district as defined in KRS 216B.455 and is to the same campus as a licensed~~
18 ~~psychiatric residential treatment facility].~~

19 (2) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant
20 to KRS 216B.095(f), the Office of Health Policy shall grant nonsubstantive review status
21 to an application for which a certificate of need is required if:

22 (a) The proposal involves the establishment or expansion of a health facility or
23 health service for which there is not a component in the State Health Plan;

(b) The proposal involves an application from a hospital to reestablish the number of acute care beds that it converted to nursing facility beds pursuant to KRS 216B.020(4), if the number of nursing facility beds so converted are delicensed;

(c) The proposal involves an application to relocate or transfer licensed acute care beds, not including neonatal Level III beds, from one (1) existing licensed hospital to another existing licensed hospital within the same area development district and the requirements established in this paragraph are met.

1.a. There shall not be an increase in the total number of licensed acute care beds in that area development district; and

b. The hospital from which the beds are relocated delicensures those beds.

2. If neonatal Level II beds are relocated or transferred pursuant to this paragraph:

a. The receiving hospital shall have an existing licensed Level II or Level III neonatal unit;

b. A minimum of four (4) beds shall be relocated; and

c. The relocation shall not leave the transferring hospital with less than four (4) neonatal Level II beds unless the relocated beds represent all of its neonatal Level II beds;

(d) The proposal involves an application by an existing licensed hospital to:

1. Convert licensed psychiatric or chemical dependency beds to acute care beds, not including special purpose acute care beds such as neonatal Level II beds or neonatal Level III beds;

2. Convert and implement the beds on-site at the hospital's existing licensed facility;

and

1 3. Delicense the same number of psychiatric or chemical dependency beds that are
2 converted.

3 (e) The proposal involves an application by an existing licensed hospital providing
4 inpatient psychiatric treatment to:

5 1. Convert psychiatric beds licensed for use with geriatric patients to acute care
6 beds, not including special purpose acute care beds such as neonatal Level II beds or
7 neonatal Level III beds;

8 2. Implement the beds on-site at the existing licensed hospital; and

9 3. Delicense the same number of converted beds;

10 (f) The proposal involves an application to transfer or relocate existing certificate of
11 need approved nursing facility beds between certificate of need approved nursing
12 facilities or from a certificate of need approved nursing facility to a proposed nursing
13 facility and the requirements established in this paragraph are met.

14 1. The selling or transferring facility has a certificate of need nursing facility bed
15 inventory of at least 250 beds;

16 2. The transfer or relocation takes place within the same Area Development District;

17 3. The application includes:

18 a. A properly completed OHP - Form 9, Notice of Intent to Acquire a Health Facility
19 or Health Service, incorporated by reference in 900 KAR 6: 055; and

20 b. Evidence of the selling or transferring entity's binding commitment to sell or
21 transfer upon approval of the application; and

22 4. A certificate of need approved nursing facility shall not sell or transfer more than
23 fifty (50) percent of its certificate of need approved nursing facility beds;

1 ~~(g) [The proposal involves an application to establish a nursing facility with no more~~
2 ~~than sixty two (62) nursing facility beds and the requirements established in this~~
3 ~~paragraph are met.~~

4 ~~— 1. The applicant is an existing licensed psychiatric hospital operated by the~~
5 ~~Commonwealth of Kentucky;~~

6 ~~— 2. The proposed nursing facility shall be located on the psychiatric hospital's~~
7 ~~campus; and~~

8 ~~— 3. The letter of intent is filed no later than March 1, 2010 and the application is filed~~
9 ~~no later than March 31, 2010;~~

10 ~~— (h) The proposal involves an application to establish a psychiatric hospital with no~~
11 ~~more than fifty (50) psychiatric beds and the requirements established in this paragraph~~
12 ~~are met.~~

13 ~~— 1. The letter of intent is filed no later than March 1, 2010 and the application is filed~~
14 ~~no later than March 31, 2010;~~

15 ~~— 2. The proposed psychiatric hospital shall be located in an area development district~~
16 ~~(ADD) which does not contain a licensed psychiatric hospital;~~

17 ~~— 3. The applicant proposes to provide services only to individuals between the ages~~
18 ~~of four (4) and twenty one (21);~~

19 ~~— 4. The patient population to be served shall be limited to children with documented~~
20 ~~evidence of mental retardation or a developmental disability as defined under 907 KAR~~
21 ~~1:145; physical aggression; or inappropriate sexual behavior;~~

22 ~~— 5. The facility shall not refuse to admit a patient or discharge a patient due to the~~
23 ~~presence of the characteristics described in subparagraphs 3 and 4 of this paragraph;~~

~~6. The proposed psychiatric hospital shall have on staff a board eligible or board certified child psychiatrist who maintains responsibility for admissions and treatment.~~

~~The board eligible child psychiatrist shall be a doctor of psychiatry who has been board certified in general psychiatry by the American Board of Psychiatry and Neurology and has completed a two (2) year fellowship in child psychiatry; and~~

~~7. The application shall include all of the following:~~

~~a. The specific number of psychiatric beds proposed;~~

~~b. An inventory of current psychiatric services in the Area Development District;~~

~~c. Clear admission and discharge criteria;~~

~~d. Linkage agreements with other child and adolescent serving agencies in the proposed service areas, including all regional interagency councils, community mental health centers, the Department for Community Based Services, and major referring school systems. These agreements shall demonstrate a commitment by these agencies and the hospital to joint treatment and discharge planning as appropriate; and~~

~~e. Documentation of linkage agreements for the provision for case management services if necessary after discharge. A case manager:~~

~~(i) May be on the hospital's staff; and~~

~~(ii) Shall be closely involved in cases from treatment planning onward;~~

~~(i)] The proposal involves an application to establish a therapeutic cardiac catheterization program and the requirements established in this paragraph are met.~~

1. The applicant is an acute care hospital which was previously granted a certificate of need to participate in a primary angioplasty pilot project and was evaluated after the first two (2) years of operation by an independent consultant who determined the

1 hospital successfully demonstrated good therapeutic cardiac catheterization outcomes.

2 2. The applicant shall document that the nursing and technical catheterization
3 laboratory staff are experienced and participate in a continuous call schedule.

4 3. The applicant shall document that the catheterization laboratory shall be
5 equipped with optimal imaging systems, resuscitative equipment, and intra-aortic
6 balloon pump support.

7 4. The applicant shall document that the cardiac care unit nurses shall be proficient
8 in hemodynamic monitoring and intra-aortic balloon pump management.

9 5. The applicant shall document formalized written protocols in place for immediate
10 and efficient transfer of patients to an existing licensed cardiac surgical facility.

11 6. The applicant shall utilize a Digital Imaging and Communications in Medicine
12 (DICOM) standard image transfer system between the hospital and the backup surgical
13 facility.

14 7. The applicant shall employ an interventional program director who has performed
15 more than 500 primary PCI procedures and who is board certified by the American
16 Board of Internal Medicine in interventional cardiology.

17 8. The applicant shall document that each cardiologist performing the therapeutic
18 catheterizations shall perform at least seventy-five (75) PCIs per year.

19 9. The applicant shall document the ability to perform at least 200 interventions per
20 year, with ideal minimum of 400 interventions per year by the end of the second year of
21 operation.

22 10. The applicant shall participate in the American College of Cardiology National
23 Cardiovascular Data Registry quality measurement program.

1 11. The applicant shall report therapeutic cardiac catheterization data annually to
2 the Cabinet for Health and Family Services.

3 12. The application shall document the applicant's ability to produce therapeutic
4 cardiac catheterization outcomes which are within two (2) standard deviations of the
5 national means for the first two (2) consecutive years; or

6 (h)(4) The proposal involves an application to transfer or relocate existing certificate
7 of need approved nursing facility beds from one (1) long-term care facility to another
8 long-term care facility and the requirements established in this paragraph are met.

9 1. The selling or transferring facility fails to meet regulations promulgated by the
10 Centers for Medicare and Medicaid Services at 42 C.F.R. 483.70(a)(8) requiring nursing
11 facilities to install sprinkler systems throughout their buildings;

12 2. The selling or transferring facility may sell or transfer portions of its total bed
13 component to one (1) or more existing nursing facility;

14 3. The facility acquiring the beds shall be located in a county contiguous to that of
15 the selling or transferring facility;

16 4. The selling or transferring facility shall be licensed only for nursing facility beds at
17 the time of transfer or application to transfer and shall not sell or transfer more than
18 thirty (30) of its licensed nursing facility beds to an individual facility; and

19 5. The application shall include a properly completed OHP - Form 9, Notice of Intent
20 to Acquire a Health Facility or Health Service, incorporated by reference in 900 KAR
21 6:055.

22 (3) If an application is denied nonsubstantive review status by the Office of Health
23 Policy, the application shall automatically be placed in the formal review process.

1 (4) If an application is granted nonsubstantive review status by the Office of Health
2 Policy, notice of the decision to grant nonsubstantive review status shall be given to the
3 applicant and all known affected persons.

4 (5)(a) If an application is granted nonsubstantive review status by the Office of
5 Health Policy, any affected person who believes that the applicant is not entitled to
6 nonsubstantive review status or who believes that the application should not be
7 approved may request a hearing by filing a request for a hearing within ten (10) days of
8 the notice of the decision to conduct nonsubstantive review.

9 (b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive
10 review hearings.

11 (c) Nonsubstantive review applications shall not be comparatively reviewed but may
12 be consolidated for hearing purposes.

13 (6) If an application for certificate of need is granted nonsubstantive review status by
14 the Office of Health Policy, there shall be a presumption that the facility or service is
15 needed and applications granted nonsubstantive review status by the Office of Health
16 Policy shall not be reviewed for consistency with the State Health Plan.

17 (7) Unless a hearing is requested pursuant to 900 KAR 6:090, the [The] Office of
18 Health Policy [cabinet] shall approve applications for certificates of need that have been
19 granted nonsubstantive review status [~~by the Office of Health Policy~~] if:

20 (a) The application does not propose a capital expenditure; or

21 (b) The application does propose a capital expenditure, and the Office of Health
22 Policy [cabinet] finds the facility or service with respect to which the capital expenditure
23 proposed is needed, unless the cabinet finds that the presumption of need provided for

1 in subsection (6) of this section has been rebutted by clear and convincing evidence by
2 an affected party.

3 (8) The cabinet shall disapprove an application for a certificate of need that has
4 been granted nonsubstantive review if the cabinet finds that the:

5 (a) Applicant is not entitled to nonsubstantive review status; or

6 (b) Presumption of need provided for in subsection (6) of this section has been
7 rebutted by clear and convincing evidence by an affected party.

8 (9) A decision to ~~[The cabinet shall]~~ approve or disapprove an application which has
9 been granted nonsubstantive review status shall be rendered ~~[by the Office of Health~~
10 ~~Policy]~~ within thirty-five (35) days of the date ~~[that public notice is given]~~ that
11 nonsubstantive review status has been granted.

12 (10) If a certificate of need is disapproved ~~[denied]~~ following nonsubstantive review,
13 the applicant may:


14 (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and
15 900 KAR 6:065;

16 (b) Request that the application be placed in the next cycle of the formal review
17 process; or

18 (c) Seek judicial review pursuant to KRS 216B.115.

900 KAR 6:075

REVIEWED:

 7-1-11

Carrie Banahan, Executive Director Date
Office of Health Policy

APPROVED:

 7/13/11

Janie Miller, Secretary Date
Cabinet for Health and Family Services

900 KAR 6:075

PUBLIC HEARING AND COMMENTS:

A public hearing on this administrative regulation shall, if requested, be held on August 22, 2011, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 15, 2011, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2011. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:075

Contact Person: Carrie Banahan or Chandra Venettozzi, (502) 564-9589

1. Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the guidelines and considerations for nonsubstantive review of applications for the certificate of need program.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 194A.030, 194A.050, 216B.040(2)(a)1.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 194A.030, 194A.050, 216B.040(2)(a)1 by establishing the considerations for nonsubstantive review of certificate of need applications
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 194A.030, 194A.050, 216B.040(2)(a)1 by establishing the considerations for nonsubstantive review of certificate of need applications.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: The amendment will delete language that is no longer needed such as change of location for a psychiatric residential treatment facility, establishment of a nursing facility with no more than sixty-two nursing facility beds. The amendment will also provide flexibility so that decisions to approve or disapprove applications for certificate of need may be signed by the Executive Director of the Office of Health Policy.
- (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to eliminate unnecessary language and provide more flexibility so that decisions to approve or disapprove applications for certificate of need may be signed by the Executive Director of the Office of Health Policy.
- (c) How the amendment conforms to the content of the authorizing statutes: The amendment carries out the requirement of KRS 194A.030, 194A.050, 216B.040(2)(a)1 by establishing the considerations for nonsubstantive review of certificate of need applications.

- (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide more flexibility so that decisions to approve or disapprove applications for certificate of need may be signed by the Executive Director of the Office of Health Policy.
- 3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file a certificate of need application. Approximately 100 entities file a certificate of need application each year.
- 4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the considerations for nonsubstantive review of certificate of need applications set forth in the administrative regulation are currently established and operational, no new action will be required of regulated entities to comply with this regulation.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the considerations for nonsubstantive review of certificate of need applications set forth in the administrative regulation are currently established and operational, no cost will be incurred by regulated entities to comply with this regulation.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This administrative regulation will provide potential health care providers with a mechanism to establish health care facilities and services in compliance with KRS 216B and will provide more flexibility so that decisions to approve or disapprove applications for certificate of need may be signed by the Executive Director of the Office of Health Policy.
- 5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
- 6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:075 Contact Person: Carrie Banahan or Chandra Venettozzi

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned, controlled or proposed healthcare facilities or services as well as the Office of Health Policy within the Cabinet for Health and Family Services.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050, 216B.040(2)(a)1.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

- (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No impact to revenues.
- (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenues will be generated to state or local government.
- (c) How much will it cost to administer this program for the first year? None.
- (d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None
Expenditures (+/-): None
Other Explanation: None